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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/666,886 | SEGAL ET AL. | |
| | Examiner | Art Unit | |
| | Emily Le | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *11 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of Claims*

1. Claims 1-11 are pending. Claim 4 is withdrawn from examination because the claim is directed to a ligand for CD40, and not a ligand for a cytokine receptor as elected. Claims 1-3 and 5-11 are under examination.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-3 and 5-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to the written description rejection set forth in the previous office action, Applicant alleges that the Office has improperly imported limitations into the claims when the Office interprets the term "vaccine " to encompass medicaments that provides protection, and argues that the "claims, i.e. a vaccine composition" are not defined by the ability of the vaccine composition to provide "protection". Applicant submits that the claims define a composition that is in a form suitable for administration to a subject.

Applicant's submission has been considered, however, it is not found persuasive. Applicant is reminded that one aspect of the enablement analysis includes a consideration of the full breadth of the invention claimed. The claims recite a "vaccine composition". And the broadest and reasonable interpretation of the term "vaccine" includes a medicament that has at least some protective efficacy. If Applicant's intention is to claim a composition that is suitable for administration to a subject, such as a pharmaceutical composition, then the claims should be amended to reflect this intention.

Applicant also submits that Applicant does have possession of a genus of cells since the specification does disclose various types of cells, and as noted by the Office when the Office states that the specification provides a generic list of cells.

Applicant's submission has been considered, however, it is not found persuasive. In the instant, while it has been recognized that Applicant's disclosure does set forth a list of generic cells, however, Applicant has not provided a listing or identification of cells that commensurate with the claimed invention, which are cells that have some protective efficacy.

In summation, all of Applicant's submission has been considered, however, it is not found persuasive. Thus, the claims remain rejected.

Additionally, claim 3 is further rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to the rejection, Applicant submits that it is well known in the art, as evidenced by Exhibits A-J, which amino acids of GM-CSF molecules are necessary, and which are not necessary for receptor binding and/or bioactivity.

Applicant's submission has been considered, however, it is not found persuasive. The instant rejection is directed at the limitation recited in the cited claims, wherein the second amino acid sequence has at least five contiguous amino acids of GM-CSF.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient description of a representative number of species by i) actual reduction to practice, ii) reduction to drawings, or iii) disclosure of relevant identifying characteristics. Examples of factors to be considered for the latter requirement include: a) disclosure of complete or partial structure, b) physical and/or chemical properties, c) functional characteristics, d) correlation between structure and function, and e) methods of making.

Each of the listed criteria is addressed in turn below.

i) sufficient description of a representative number of species by actual reduction to practice: The specification does not set forth the amino acid sequence of GM-CSF. The specification does not teach of a single amino acid sequence that is less that the complete GM-CSF polypeptide. Ergo, the specification does not provide for sufficient number of species by actual reduction to practice.

ii) sufficient description of a representative number of species by reduction to drawings: The specification does not contain any drawings. Thus, there is insufficient description of a representative number of species by reduction to drawings.

iii) sufficient description of a representative number of species by disclosure of relevant identifying characteristics: a) disclosure of complete or partial structure: The complete structure of the naturally occurring GM-CSF polypeptide is not provided in the specification, however, the Office recognizes that the complete amino acid sequence of GM-CSF can be readily ascertain from the art—as further evidenced by Exhibits A-J submitted by Applicant; b) physical and/or chemical properties: the claims require that the polypeptide have at least 5 amino acids sequence derived from GM-CSF, however, neither the claims nor the specification set forth any guidance pertaining to which amino acid fragments to use with the claimed invention; c) functional characteristics: no function is specified in the claims or the specification; d) correlation between structure and function: no structural and functional correlation can be ascertained because neither the claims nor the specification set forth a function for the polypeptide.

In the instant, Applicant has taught only the full length GM-CSF polypeptide. Applicant has not set forth any teachings demonstrating that Applicant was in possession of any GM-CSF fragments comprising at least 5 amino acids. There is nothing provided in the specification that would lead the skilled artisan to recognize that Applicant was in possession of anything more than the full length GM-CSF polypeptide. Hence, the claims are rejected under 35 U.S.C. 112, first paragraph, written description, for insufficient possession of GM-CSF fragments comprising at least 5 amino acids.

4. Claims 1-3 and 5-11 are rejected under 35 U.S.C. 112, first paragraph because the specification is not enabling for the full scope that is instantly claimed.

In response to the enablement rejection set forth in the previous office action, Applicant alleges that the Office has improperly imported limitations into the claims when the Office interprets the term "vaccine " to encompass medicaments that provides protection, and argues that the "claims, i.e. a vaccine composition" are not defined by the ability of the vaccine composition to provide "protection". Applicant submits that the claims define a composition that is in a form suitable for administration to a subject, and ones that provide a heightened immune response. Applicant also submits that the specification provides several working examples, utilizing different cell types that demonstrate the ability of the claimed vaccine composition to provided a heightened immune response. In addition, Applicant submits a declaration by Andrew Segal under 37 C.F.R. § 132, that shows that three additional cell types can be used in the vaccine composition as claimed and which provide a heightened immune response.

Applicant's submission has been considered, however, it is not found persuasive. The claims recite a "vaccine composition". As part of the enablement analysis, the full breadth of the invention claims has to be considered. The broadest and reasonable interpretation of the term "vaccine" includes a medicament that has at least some protective efficacy. Thus, the claims are interpreted to encompass a vaccine composition that has at least some protective efficacy. This interpretation is in accordance with Applicant's disclosure. On page 162, Applicant teaches that the composition recited in the claims should be administered at an amount that is necessary

to provide the desired degree of protection. On the same page, the specification also teaches that periodic boosters of the composition can be administered to maintain the desired levels of protective immunity. Thus, in view of the language that is recited in the claims, accompanied by the teachings provided in the specification, the full scope of Applicant's claimed invention extends beyond the breadth that Applicant presented in Applicant's recent submission.

In the instant, while it may be true that Applicant's composition is capable of enhancing immune stimulation, the specification must also be enabling for the full breadth of the claimed invention. In the instant, Applicant has not set forth any guidance for the skilled artisan to synergize the observed enhanced immune stimulation into one that provides some degree of protection. In the absence of any such guidance or teachings, the skilled artisan would not be able to practice the full scope of the claimed invention without the undue burden of experimentation.

Furthermore, the specification does not teach the skilled artisan how to overcome the complexities that hinder or defer the development of a cancer vaccine. The complexities that challenge the discovery of tumor vaccines include antigen change, immune escape, and the inability of target tumor antigen to induce a high level of immunogenicity, as evidence by Yu et al.[1] Furthermore, at the time of filing for the instantly claimed invention, the state of the art notes that a cancer vaccine that can reliably increase a patient survival or induce tumor destruction does not exist. [Abstract of Yu et al.] Moreover the specification does not teach the skilled artisan how to properly

activate and prolong the activation of antitumor T cells, which is recognized in the art as the crucial missing piece of the immunotherapy--a method of treatment for cancer, puzzle an significant barrier in developing an effective therapeutic vaccine. [Last paragraph of Yu et al.] In addition to the above provided summation on the state of cancer vaccine, Berzofsky et al.[2] also discusses several major hurdles that exist in the development of cancer vaccines. Though some of the hurdles that Berzofsky et al. discusses are the same as that of Yu et al., Berzofsky et al. provides a listing of other hurdles. These include: i) identification of antigens that focus the exquisite specificity of the immune system on cancer cells without harming normal cells; ii) development of methods to induce an immune response sufficient to eradicate the tumor in the face of self-tolerance to many tumor antigens; and iii) overcoming mechanisms by which tumors evade the host immune response. In the instant, the specification does not provide any guidance as to how the skilled artisan can overcome or circumvent the hurdles that are discussed by Berzofsky et al.

Additionally, the state of the art notes that to take advantage of the immune system's specification against cancer, the skilled artisan must find antigens that clearly mark the cancer cells as different from the host cells, as noted by Berzofsky et al. In the instant, no such teaching or guidance is provided in the specification. Additionally, the specification also does not teach the skilled artisan how to overcome instances where tumor antigens of interest are not expressed on the surface of the tumor cells, which is

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[1] Yu et al. Cancer vaccines: progress reveals new complexities. The Journal of Clinical Investigation, 08/02, Vol. 110, No. 3, 289-294.
[2] Berzofsky et al. Progress on new vaccine strategies for the immunotherapy and prevention of cancer. The Journal of Clinical Investigation. June 2004, Vol. 113, No. 11, 1515-1525.

a challenge that has been encountered in the discovery of a cancer vaccine. [2nd paragraph, left column of page 1515, of Berzofsky et al.]

Thus, in view of the very limited teaching that is provided in the specification and the existence of many major challenges identified in the art pertaining to the development of a cancer vaccines, the skilled artisan would not know how to make and use the full scope of the claimed invention without undue experimentation.

Regarding the declaration of Andrew Segal, typically, in assessing the weight to be given expert testimony, the examiner may properly consider, among other things, 1) the nature of the fact sought to be established, 2) the strength of any opposing evidence, 3) the interest of the expert in the outcome of the case, and 4) the presence or absence of factual support for the expert's opinion. See Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985), cert. denied, 475 U.S. 1017(1986).

In the instant, the fact established by Andrew Segal is not the same as the one being sought for the enablement rejection. Segal establishes that compositions similar to those recited in the claims are capable of enhancing immune stimulation. However, the issue here is not whether or not Applicant's claimed composition is capable of enhancing immune stimulation. The issue here has always been whether Applicant's claimed composition is protective. Thus, the fact sought to be established here is whether the claimed composition is protective. The fact sought here is different from those established by the declaration of Andrew Segal. In the instant, the Office finds

that the declaration of Andrew Segal is deficient because it fails to provide evidence demonstrating the protective efficacy of the claimed composition.

In summation, Applicant's submission has been carefully considered, however, it is not found persuasive.

***Double Patenting***

5. In response to the double patenting rejections set forth in the previous office action, and restated below, Applicant submits that a terminal disclaimer will be timely filed upon notification of allowable subject matter by the Office.

Applicant's intention is noted. However, until the rejections are properly addressed, with the submission of a terminal disclaimer, all double patenting rejections are maintained for the reason(s) set forth in the record.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/666833.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a vaccine composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a vaccine composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The difference between the two claims is the recitations "cell" and "antigen bearing target".

However, the recitation "cell" does fall entirely within the scope of the recitation "antigen bearing target". Thus, this aspect of the claim is anticipated by those recited in the conflicting patent application.

The other difference noted between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and " first amino acid sequence which can bind to a carbohydrate".

However, "first amino acid sequence which can bind to a carbohydrate" falls entirely within the scope of the recitation "first amino acid sequence comprising a cell-surface binding moiety".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 10/667193.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a vaccine composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The difference between the two claims is that the claims in the instant application is directed at a product, and the claims in the conflicting patent application is directed at a method of using the same product as those provided in the claims in the instant application.

However, because the claims in the conflicting patent application is directed at a method of using a product that is the same as those provided in the claims in the instant application, it is clear that the conflicting patent application has possession of the instantly claimed product. Ergo, because the conflicting patent application has possession of the instantly claimed product, the conflicting patent application anticipates the instantly claimed product.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-78 of copending Application No. 10/645000.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a vaccine composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a vaccine composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide, wherein the ligand is selected from the group consisting of a ligand for a cytokine receptor, a ligand for CD40, a ligand for an adhesion molecule, a ligand for a defensin receptor, a ligand for heat shock protein receptor, a ligand for a T cell costimulatory molecule, a ligand for a counterreceptor for a T cell costimulatory molecule.

The difference between the two claims is the recitations "cell" and "antigen bearing target".

However, the recitation "cell" does fall entirely within the scope of the recitation "antigen bearing target". Thus, this aspect of the claim is anticipated by those recited in the conflicting patent application.

The other difference noted between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and " first amino acid sequence which can bind to a carbohydrate".

However, "first amino acid sequence which can bind to a carbohydrate" falls entirely within the scope of the recitation "first amino acid sequence comprising a cell-surface binding moiety".

The one last difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a second amino acid sequence that is of a ligand for a cell surface polypeptide, wherein the ligand is selected from the group consisting of a ligand for a cytokine receptor, a ligand for CD40, a ligand for an adhesion molecule, a ligand for a defensin receptor, a ligand for heat shock protein receptor, a ligand for a T cell costimulatory molecule, a ligand for a counterreceptor for a T cell costimulatory molecule."

However, the ligands recited in claim 1 of the conflicting patent applications are all ligands for a cell surface polypeptide of a leukocyte. In the instant, claim 1 of the conflicting patent application falls entirely within the scope of claim 1 of the examined claimed. Hence, claim 1 of the conflicting patent application anticipates this aspect of the claim 1 of the instant patent application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/224661 in view of Faulkner et al.[3]

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a vaccine composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a fusion polypeptide comprising a lectin that is capable of binding a carbohydrate and includes the HA carbohydrate binding domain of an influenza virus hemagglutinin and a naturally occurring GM-CSF molecule.

The difference between the two sets of claims that claim 1 of the conflicting patent application does not recite the presence of a cell with the fusion polypeptide.

However, the art teaches the use of compositions such as those recited in claim 1 of the conflicting patent application as adjuvants in vaccines, as evidenced by Faulkner et al. [Page 713]

Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to include a cell, e.g., autologous tumor cells, with the

[3] Faulkner et al. IL-2 linked to a peptide from influenza hemagglutinin enhances T cell activation by

composition of the conflicting patent application. One of ordinary skill in the art would have been motivated to do so to boost the immune response to tumor antigen.

The other difference between the two set of claims is that claim 1 of instant patent application is directed to a genus of fusion polypeptides, whereas, claim 1 of the conflicting patent application is directed to a species of fusion polypeptides. The fusion polypeptide of claim 1 of the conflicting patent application falls entirely within the scope of the claim 1 of the instant patent application. The lectin that is capable of binding a carbohydrate and includes the HA carbohydrate binding domain of an influenza virus hemagglutinin is the first amino acid sequence that comprises a cell-surface binding moiety, and the naturally occurring GM-CSF molecule is the second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-69 of copending Application No. 10/666898 in view of Faulkner et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a vaccine composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface

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affecting the antigen-presentation function of bone marrow-derived dendritic cells. International

binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a nucleic acid composition encoding a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The difference between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and "carbohydrate binding domain".

However, a carbohydrate binding domain is encompassed by the generic recitation "first amino acid sequence comprising a cell-surface binding moiety".

The other difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two sets of claims that claim 1 of the conflicting patent application does not recite the presence of a cell with the fusion polypeptide.

However, the art teaches the use of compositions such as those recited in claim 1 of the conflicting patent application as adjuvants in vaccines, as evidenced by Faulkner et al. [Page 713]

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Immunology, 2001, Vol. 13, No. 6, 713-721.

Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to include a cell, e.g. autologous tumor cells, with the composition of the conflicting patent application. One of ordinary skill in the art would have been motivated to do so to boost the immune response to tumor antigen.

The last difference noted between the two is that claim 1 of the instant patent application is directed at a fusion polypeptide, and claim 1 of the conflicting patent application is directed at a nucleic acid composition that encodes the instantly claimed fusion polypeptide.

However, it would have been prima facie obvious for one of ordinary skill in the art to obtain the coding sequence of the fusion to express/make the fusion polypeptide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-147 of copending Application No. 10/666885 in view of Faulkner et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a vaccine composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a vector comprising a nucleic acid molecule composition encoding a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The difference between the two claims is the recitation "first amino acid sequence comprising a cell-surface binding moiety" and "carbohydrate binding domain".

However, a carbohydrate binding domain is encompassed by the generic recitation "first amino acid sequence comprising a cell-surface binding moiety".

The other difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two sets of claims that claim 1 of the conflicting patent application does not recite the presence of a cell with the fusion polypeptide.

However, the art teaches the use of compositions such as those recited in claim 1 of the conflicting patent application as adjuvants in vaccines, as evidenced by Faulkner et al. [Page 713]

Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to include a cell, e.g. autologous tumor cells, with the

composition of the conflicting patent application. One of ordinary skill in the art would have been motivated to do so to boost the immune response to tumor antigen.

The last difference noted between the two is that claim 1 of the instant patent application is directed at a fusion polypeptide, and claim 1 of the conflicting patent application is directed at a vector construct comprising a nucleic acid composition that encodes the instantly claimed fusion polypeptide.

However, it would have been prima facie obvious for one of ordinary skill in the art to place the vector expression construct in a cell to express/make the fusion polypeptide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-68 of copending Application No. 10/666871, in view of Faulkner et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a vaccine composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The difference between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and "carbohydrate binding domain".

However, a carbohydrate binding domain is encompassed by the generic recitation "first amino acid sequence comprising a cell-surface binding moiety".

The other difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two sets of claims that claim 1 of the conflicting patent application does not recite the presence of a cell with the fusion polypeptide.

However, the art teaches the use of compositions such as those recited in claim 1 of the conflicting patent application as adjuvants in vaccines, as evidenced by Faulkner et al. [Page 713]

Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to include a cell, e.g. autologous tumor cells, with the composition of the conflicting patent application. One of ordinary skill in the art would have been motivated to do so to boost the immune response to tumor antigen.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-77 of copending Application No. 10/666834.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a vaccine composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide. And the antigen bearing target comprises at least one of the following: a viral antigen, a bacterial antigen, a fungal antigen, a parasite antigen, a prion antigen.

The difference between the two claims is the recitations "cell" and "antigen bearing target".

However, the recitation "cell" does fall entirely within the scope of the recitation "antigen bearing target". Thus, this aspect of the claim is anticipated by those recited in the conflicting patent application.

The difference noted between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and " first amino acid sequence which can bind to a carbohydrate".

However, a carbohydrate binding domain is encompassed by the generic recitation "first amino acid sequence comprising a cell-surface binding moiety".

The other difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two sets of claims that claim 1 of the conflicting patent application requires the antigen bearing target comprises at least one of the following: a viral antigen, a bacterial antigen, a fungal antigen, a parasite antigen, a prion antigen; whereas claim 1 of the instant patent application does not require the same.

However, the antigen bearing target of claim 1 of the instant patent application is generic to the an antigen bearing target comprises at least one of the following: a viral

antigen, a bacterial antigen, a fungal antigen, a parasite antigen, a prion antigen of claim 1 of the conflicting patent application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-77 of copending Application No. 10/667166.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a vaccine composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide.

The difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two claims is the recitations "cell" and "antigen bearing target".

However, the recitation "cell" does fall entirely within the scope of the recitation "antigen bearing target". Thus, this aspect of the claim is anticipated by those recited in the conflicting patent application.

The other difference noted between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and " first amino acid sequence which can bind to a carbohydrate".

The other difference noted between the two claims is the recitations "first amino acid sequence which can bind to a carbohydrate" vs. "first amino acid sequence comprising a cell-surface binding moiety".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 1-3 and 5-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-82 of copending Application No. 10/668073.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a vaccine composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide.

The difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two claims is the recitations "cell" and "antigen bearing target".

However, the recitation "cell" does fall entirely within the scope of the recitation "antigen bearing target". Thus, this aspect of the claim is anticipated by those recited in the conflicting patent application.

The other difference noted between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and " first amino acid sequence which can bind to a carbohydrate".

However, a carbohydrate binding domain is encompassed by the generic recitation "first amino acid sequence comprising a cell-surface binding moiety".

The other difference noted between the two claims is that the claims in the instant application is directed at a product, and the claims in the conflicting patent application is directed at a method of using the same product as those provided in the claims in the instant application.

However, because the claims in the conflicting patent application is directed at a method of using a product that is the same as those provided in the claims in the instant application, it is clear that the conflicting patent application has possession of the instantly claimed product. Ergo, because the conflicting patent application has possession of the instantly claimed product, the conflicting patent application anticipates the instantly claimed product.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusion***

17. No claims are allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

19. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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E.Le